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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,085	09/22/2003	Gary L. Bowlin	49122-0162	1270

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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1652

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/668,085

Applicant(s)

BOWLIN ET AL.

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,6,9 and 24-36 is/are pending in the application.
- 4a) Of the above claim(s) 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,6,9,24-32 and 36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Because this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on January 8, 2007 has been entered.

Claims 1, 24-26, 28 have been amended. Claim 5 has been canceled; claims 2-4, 7-8 and 10-23 were canceled previously. Claim 36 has been added. Claims 33-35 were withdrawn in a previous Office action as being drawn to a non-elected invention. Accordingly, claims 1, 6, 9, 24-32 and 36 are examined on the merits herewith.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

In view of Applicants' amendments to the claims, the rejections under 35 USC § 102 (Coffee, Martin et al., Doshi et al., Murphy et al. as evidenced by Koseki et al.) are withdrawn.

Claim Rejections - 35 USC § 103

Claims 1, 6, 9, 24-32 are again rejected, and claim 36 is rejected, under 35 U.S.C. 103(a) as being unpatentable over Coffee (WO 98/03267), Martin et al. (US 4,043,331), Doshi et al. ("Electrospinning process and applications of electrospun fibers," J Electrostatics 35:151-

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160, 1995) and Murphy et al. (US 2002/0172705) in view of Mechanic (US 5,332,475). This rejection was discussed in the previous Office action.

Applicants assert that the claimed composition requires at least one natural material and two or more synthetic materials that are simultaneously electroprocessed to form the electroprocessed material and that this is a distinct composition from those in the prior art. Applicants discuss their Examples 1 and 2, which teach the simultaneous electroprocessing of one natural polymer and two synthetic polymers.

Applicants also assert that there is no motivation in the prior art to use more than one synthetic polymer and that the immiscible materials are not part of the electroprocessed material per se. Applicants further assert that one of ordinary skill in the art would not be motivated to combine an immiscible substance with a polymer solution because the individual components are immiscible and that Martin et al. and Doshi et al. teach away from combining an immiscible substance and a polymer solution. Additionally, Applicants assert that these two references do not disclose electroprocessing a natural material, that Coffee does not disclose electroprocessing one natural material and two synthetic materials, and that the cited references do not teach or suggest that this combination of materials would result in an effective composition of one natural polymer and two synthetic polymers.

In reply, regarding the simultaneous electroprocessing of one natural polymer and two synthetic polymers, i.e., preparing a solution of these three polymers and electroprocessing that solution, Applicants appear to be arguing the specification- Examples 1 and 2- not the claims. The cited references do not disclose or suggest this feature, but it is not recited in the claims. Because this feature is not a claim limitation, this feature does not distinguish the claimed invention over the prior art. As previously discussed, the claims read on a composition

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comprising layers of different electroprocessed materials, and this feature is clearly taught by the prior art.

In the previous Office action, the claimed composition was rejected under the doctrine of In re Kerkhoven (it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to make a third composition that is to be used for the very same purpose, as the idea of combining them flows logically from their having been individually taught in the prior art), and this point still applies. It would have been prima facie obvious to one of ordinary skill in the art at the time that the invention was made to combine the teachings of the references to produce an electroprocessed material comprising one natural material and two synthetic materials. Each of these electroprocessed materials has been individually taught in the prior art to be successful when made into materials that are used for the same purpose as Applicants' material, i.e., a wound dressing (wound care product). One of ordinary skill in the art would have reasonably expected to obtain an electroprocessed material used in the same ways as the claimed material with any one or with all three of the prior art polymers, i.e., a protein (collagen) and two synthetic polymers (polyvinyl alcohol and polylactide), because all of these polymers have been demonstrated in the prior art to be effective materials for wound dressings or implants, in particular wound dressings that promote cell growth and tissue repair.

Additionally, as previously discussed, the strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. In re Sernaker, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983). Martin et al. and Murphy et al. teach that each material in the composition is selected because of its desired biological, physical and/or

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chemical properties and that a selected combination of materials yields a composition that has the properties desired, e.g., permeability, thickness, biocompatibility and biodegradability. One of ordinary skill in the art would have recognized the benefits of a composition of electroprocessed materials comprising a natural material such as collagen for its biocompatibility, biodegradability and promotion of cell growth (as taught by Murphy et al., see paragraphs 1, 2, 22, 33 and 34) and a synthetic material such as polyurethane, which is a wettable polymer commonly used in wound dressings. Polyurethane inhibits bleeding by promoting clotting, is porous and has a high surface area, which allows therapeutic substances to penetrate and blood from the wound to drain (see Martin et al., col. 2, lines 9-34). The synthetic polymers polyvinyl alcohol and polylactide have been used for a long time because they are biodegradable, inert, safe and water-soluble for simplified manufacturing (see Coffee, p. 19, last paragraph and p. 22, last paragraph). Organic solvents are more expensive than water and present waste disposal problems. Thus, one of ordinary skill in the art at the time that the invention was made would have been motivated to use a natural electroprocessed polymer and two or more synthetic electroprocessed polymers in order to produce a fibrous material that has multiple desirable properties, e.g., tissue compatibility and promotion of cell growth (from collagen), biodegradability, biocompatibility and easy manufacturing (from polyvinyl alcohol and/or polylactide), and inhibition of bleeding and improved delivery of therapeutic substances (from polyurethane). Moreover, the specification does not disclose that the claimed composition has any surprising or unexpected results that are not disclosed in the prior art.

Regarding the immiscible substance in Martin et al. and Doshi et al., as previously discussed, Doshi et al. disclose three-dimensional compositions of electrospun fibers from solutions of water-soluble polymers, biopolymers, and liquid crystalline polymers. The fibrous compositions can be used for applying insecticide to plants, as non-woven fabric, as a wound

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dressings material or as an artificial blood vessel (see p. 152, 2^d full paragraph, and p. 159).

Thus, an immiscible therapeutic or beneficial substance such as an insecticide, a wound-treating composition or blood is incorporated into the composition. Composite materials may also be produced by changing the composition of the spinning solutions successively so that layers of different polymers are deposited on top of each other. Thus, Doshi et al. do not teach trying to combine an immiscible substance with a polymer solution; they teach adding an immiscible substance (an insecticide or therapeutic agent) to a porous solid made of electrospun fibers, as do Applicants. Applicants' point is not clear. With respect to the immiscible substance, the claims do not recite an immiscible substance. The claims are broad and recite a composition comprising an electroprocessed material that is one natural material and two or more synthetic materials and a substance that is therapeutic, cosmetic or both.

Therefore, Doshi et al. do not teach away from the claimed invention.

Regarding Martin et al., as previously discussed, Martin et al. disclose electroprocessed fiber mats (abstract) for use in particular as bandages. Various polymers may be used to form the fibers, such as thermoplastic polymers, or those that may be spun from dispersions or solutions (column 4, lines 26-44; column 5, lines 21-29). Various immiscible substances such as biological components (therapeutic substances or molecules) can be incorporated within the mat (column 2, lines 35-46). When water-soluble polymers are electrospun, the polymers are first cross-linked with a suitable reagent to make them at least partially insoluble in aqueous media (see col. 4, lines 38-44). Martin et al. also disclose that fibers may be electrospun from multiple types of dissolved polymers. Each type of polymer has its own favorable properties, and combining polymers allows fibers with desired characteristics to be produced in a controlled manner (see col. 1, lines 38-56). Similarly to Doshi et al., Martin et al. teach adding an immiscible substance (a therapeutic agent) to a porous solid made of electrospun fibers, as do

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Applicants. Martin et al. disclose that solutions of different polymers may be electrospun into fibers, but they do not teach trying to combine an immiscible substance with a polymer solution. Again, Applicants' point is not clear. As discussed above, the claims do not recite an immiscible substance. They recite a composition comprising an electroprocessed material that is one natural material and two or more synthetic materials and a substance that is therapeutic, cosmetic or both. Therefore, Martin et al. do not teach away from the claimed invention.

Regarding what each reference individually does not disclose, this rejection is one of obviousness over the combination of the cited references, not a rejection of anticipation by one individual reference. With respect to a natural material (polymer), as previously discussed, Coffee discloses electrospinning collagen, Doshi et al. disclose electrospinning biopolymers, and Murphy et al. disclose electrostatic charging of collagen. As for Coffee's use of multiple electrospun polymers, as previously discussed, Coffee discloses that his mats or webs may be prepared from naturally occurring polymers such as fibrin or collagen (see p. 6, 1st full paragraph), or from synthetic biodegradable polymers such as polylactic acid, polyglycolic acid, polyvinyl alcohol or polyhydroxybutyric acid (see p. 4, 3^d paragraph), or from more than one type of electroprocessed fiber (see p. 18, 2^d full paragraph; paragraph bridging pp. 19 and 20; p. 23, 2^d full paragraph; paragraph bridging pp. 30 and 31).

Regarding claim 28, Murphy et al. disclose that the 67 nm banding pattern is a naturally occurring property of collagen (see paragraph 22). Thus, this feature has no patentable weight and does not distinguish the claimed invention over the cited art.

As discussed above, however, the prior art does not disclose the feature that one solution containing one natural polymer and two or more synthetic polymers can be made and electroprocessed, in particular, electrospun.

In view of the foregoing, the rejection of record is maintained.

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Double Patenting- Obviousness Type

In view of Applicants' amendments to the claims, this rejection is withdrawn.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, alternate Mondays off.

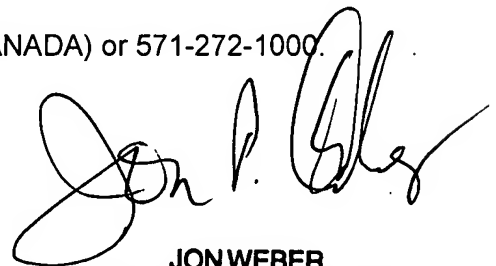
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosanne Kosson
Examiner, Art Unit 1652

rk/2007-01-16

Rosanne Kosson


JON WEBER
SUPERVISORY PATENT EXAMINER